

CLAIMS

We claim:

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1. A system that monitors respiratory events of a patient, the system comprising:
a pulse oximetry sensor and circuitry that detects oxyhemoglobin saturation and pulse
rate of the patient of the patient and produces corresponding data signals;
wherein said pulse oximetry sensor is mounted on a physiological monitoring system
that is affixed on said patient's head such that the pulse oximetry sensor detects said patient
10 conditions and produces said data signals, thereby monitoring said patient's condition.
2. A system as defined in claim 1, whereby the system monitors sleep related
obstructive respiratory events of a patient during sleep.
- 15 3. A system as defined in claim 1, further comprising a patient sensor that
produces a signal that indicates position and movement of the head of said patient.
4. A system as defined in claim 1, further comprising a microphone that
produces a data signal that indicates detected sounds produced by said patient.

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5. A system as defined in claim 1, further comprising a storage memory that is mounted on the physiological monitoring system affixed on said patient's head, and that stores the data signals produced by said pulse oximetry sensor.

5 6. A system as defined in claim 1, further comprising a computing device that receives said data signals and computes SpO₂ measurement from which a respiratory event may be identified.

10 7. A system as defined in claim 1, further comprising a data transfer interface that communicates the data signals from the system to an external computing device.

8. A system as defined in claim 1, wherein said pulse oximetry sensor is a reflectance-type sensor.

15 9. A system as defined in claim 1, further comprising a smart CPAP device that records and stores time during which the smart CPAP device is on at a prescribed pressure, thereby monitoring patient compliance with a predetermined sleep regimen.

20 10. A system as defined in claim 1, further comprising a patient respiratory airflow detector.

11. A system as defined in claim 10, wherein the airflow detector comprises a nasal cannula or a pressure transducer.

5 12. A system as defined in claim 1, wherein said system interfaces with a neuromuscular stimulation device.

13. A system as defined in claim 12, further comprising a transmission coil wherein said transmission coil uses a power source of the system.

10 14. A system as defined in claim 1, further comprising computing circuitry that receives said pulse oximetry data signals and identifies a respiratory event of the patient, wherein the computing circuitry identifies said respiratory event in response to detecting pulse oximetry data signals that indicate oxyhemoglobin desaturation.

15 15. A system as defined in claim 14, wherein the pulse oximetry data signal values necessary to indicate oxyhemoglobin desaturation and comprising a respiratory event of the patient are variable.

20 16. A system as defined in claim 14, whereby the level of oxyhemoglobin desaturation required to determine a respiratory event is variable.

17. A system as defined in claim 14, wherein the level of oxyhemoglobin desaturation required to determine a respiratory event is variable, and wherein the variable level is based on a predetermined relationship between the partial pressure of oxygen and oxyhemoglobin saturation.

18. A system as defined in claim 14, wherein the level of oxyhemoglobin desaturation required to determine a respiratory event is variable, and the variable level is based on at least one of the following criteria: peak oxyhemoglobin saturation, or nadir, or peak oxyhemoglobin resaturation.

19. A system as defined in claim 1, further including:
a computing system; and
a data transfer interface that communicates said patient physiological data signals to the computing system;

wherein the computing system analyzes the patient physiological data signals and computes time spent by the patient at each of a plurality of oxyhemoglobin saturation levels.

20. A system as defined in claim 1, further including:
a computing system; and
a data transfer interface that communicates said patient physiological data signals to the computing system;

wherein the computing system analyzes the patient physiological data signals and identifies any abnormal respiratory events of the patient, classifying the analyzed data signals into one or more types of respiratory events.

5 21. A system as defined in claim 20, further including an expert system that summarizes any identified patient respiratory events and generates a patient report.

10 ~~22. A system as defined in claim 20, further including an expert system that~~
analyzes one or more patient physiological signals and detects patient arousals that can be
used to confirm the respiratory event type classification.

15 23. A system as defined in claim 20, further including an expert system that receives the patient physiological data signals and receives patient anthropomorphic and clinical information, analyzes the data signals and patient information against a database of sleep apnea risk data, and generates a sleep apnea risk evaluation report of the patient.

 24. A system as defined in claim 1, wherein the pulse oximetry sensor comprises an active pulse oximetry sensor that applies positive pressure on the patient.

20 25. A system as defined in claim 1, wherein the physiological monitoring system is affixed to the patient by an adjustable strap.

26. A risk evaluation system that monitors sleep-related obstructive respiratory events of a patient and provides a patient risk evaluation, the system comprising:

(a) a physiological monitoring system that is affixed on said patient's head and that includes (i) a pulse oximetry sensor and circuitry that detects oxyhemoglobin saturation and pulse rate of the patient and produces corresponding data signals to detect said patient conditions, thereby monitoring said patient's condition, and includes (ii) a storage memory that stores the data signals produced by said pulse oximetry sensor;

(b) an expert system; and

(c) a data transfer interface that communicates said patient physiological data signals to the expert system;

wherein the expert system receives and analyzes the patient physiological data signals and generates a sleep apnea risk evaluation report of the patient.

27. A system as defined in claim 26, wherein the patient anthropomorphic and clinical information is analyzed and compared to a database such that the patient is assigned into one of a plurality of discrete risk categories for sleep apnea.

28. A system as defined in claim 26, further including:

a patient sensor that detects position and movement of the head of said patient and produces corresponding data signals.

29. A system as defined in claim 26, further including:

a microphone that produces a data signal that indicates detected sounds produced by said patient.

30. A system as defined in claim 26, further including a computing system that
5 receives and analyzes the patient physiological data signals and identifies any abnormal respiratory events of the patient, thereby producing one or more secondary respiratory event signals that are provided to the expert system.

31. A system as defined in claim 26, further comprising computing circuitry that
10 receives said pulse oximetry data signals and identifies a respiratory event of the patient, wherein the computing circuitry identifies said respiratory event in response to detecting pulse oximetry data signals that indicate oxyhemoglobin desaturation.

32. A system as defined in claim 26, wherein the pulse oximetry data signal
15 values necessary to indicate oxyhemoglobin desaturation and comprising a respiratory event of the patient are variable.

33. A system as defined in claim 26, whereby the level of oxyhemoglobin
desaturation required to determine a respiratory event is variable.

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34. A system as defined in claim 26, wherein the level of oxyhemoglobin
desaturation required to determine a respiratory event is variable, and wherein the variable

level is based on a predetermined relationship between the partial pressure of oxygen and oxyhemoglobin saturation.

35. A system as defined in claim 26, wherein the level of oxyhemoglobin
5 desaturation required to determine a respiratory event is variable, and the variable level is based on at least one of the following criteria: peak oxyhemoglobin saturation, or nadir, or peak oxyhemoglobin resaturation.

36. A physiological monitoring system comprising:
10 a pulse oximetry sensor and circuitry that detects oxyhemoglobin saturation and pulse rate of a patient and produces corresponding data signals;
a power source that provides electrical energy to the sensor and circuitry for operation; and
a storage memory that stores the data signals produced by said pulse oximetry sensor;
15 wherein said pulse oximetry sensor, said power source, and said storage memory are affixed on said patient's body to detect the patient conditions and produce the data signals, provide electrical power, and store the data signals, respectively, thereby monitoring said patient's condition.

20 37. A system as defined in claim 36, further including:
a patient sensor that produces a data signal that indicates position and movement of the head of said patient.

38. A system as defined in claim 36, further including:

a microphone that produces a data signal that indicates detected sounds produced by said patient.

39. A system as defined in claim 36, further comprising a data transfer interface that communicates data from the system to an external computer.

40. A system as defined in claim 36, further including an SpO₂ measuring circuit comprising multiple light sources, a photo diode that receives light from the light sources and produces a photo diode current having an AC component and a DC component, a controlled current source that produces a substantially constant current, and an analog-to-digital converter that receives a difference input signal comprising the difference between the photo diode current and the constant current, and produces a measurement current in response, wherein the constant current is selected such that the difference input signal has an AC component that is substantially equal to its DC component.

41. A system as defined in claim 36, further including a computing device that receives patient SpO₂ data produced by the pulse oximetry sensor and smooths the data, wherein the computing device smooths the data by performing one or more of the following smoothing operations: (a) applying a moving window median filter that replaces a current data sample value with a median value selected from a predetermined number of data sample

values, (b) applying a slew limitation filter that determines if two consecutive data sample values differ by more than a predetermined amount, and in response replaces a data sample value with a replacement value so as to limit the difference to no greater than the predetermined amount, and (c) applying an averaging technique that operates on multiple data sample values.

42. A system as defined in claim 41, wherein the averaging technique comprises a first-order infinite-impulse-response (IIR) filter that operates on a current data sample value and a previous data sample value.

43. A system as defined in claim 41, wherein the computing device performs multiple smoothing operations and one or more of the smoothing operations receives, as data input, smoothed data sample values produced by a different smoothing operation.

44. A system as defined in claim 36, further including a computing device that receives patient SpO₂ data produced by the pulse oximetry sensor and identifies SpO₂ data that indicates desaturation occurrences in accordance with rate of change of SpO₂ desaturation data.

45. A system as defined in claim 36, further including a computing device that receives patient SpO₂ data produced by the pulse oximetry sensor and identifies SpO₂ data

that indicates desaturation related to abnormal respiratory events by identifying changes in patient physiological data that indicate patient arousal.

46. A system as defined in claim 45, wherein the changes in patient physiological data include one or more of changes in patient heart rate, patient position and movement, and patient produced sounds.

47. A system as defined in claim 36, wherein the pulse oximetry sensor comprises an active pulse oximetry sensor that applies positive pressure on the patient.

48. A system as defined in claim 36, wherein the physiological monitoring system is affixed to the patient by an adjustable strap.

49. A method of evaluating risk of sleep apnea in a patient, the method comprising:

attaching a physiological monitoring system to the forehead of the patient, wherein the physiological monitoring system includes (a) a pulse oximetry sensor and circuitry that detects oxyhemoglobin saturation and pulse rate of the patient and produces corresponding data signals, and (b) a storage memory that stores the data signals produced by said pulse oximetry sensor; and

providing the stored data signals to an expert system that receives the stored data signals, wherein the expert system performs an analysis and generates a sleep apnea risk evaluation report of the patient.

5 50. A method as defined in claim 49, wherein the physiological monitoring system further includes a patient sensor that detects the position of the head of said patient and produces corresponding data signals and a microphone that detects snoring sounds produced by said patient and produces corresponding data signals, such that the physiological monitoring system thereby monitors said patient's condition.

10 51. A method as defined in claim 49, further including:
analyzing the patient physiological data signals and identifying any abnormal respiratory events of the patient, thereby producing one or more secondary respiratory event signals; and
15 providing the secondary respiratory event signals to the expert system for analysis in generating the evaluation report.

20 52. A method as defined in claim 49, further including the expert system receiving the patient physiological data signals and utilizing a database to perform an analysis and generate the evaluation report of the patient.

53. A method as defined in claim 52, wherein the patient anthropomorphic and clinical information is analyzed using discriminant function analysis developed using information from a database.

5 54. A method as defined in claim 52, wherein attaching the physiological monitoring system comprises attaching a system that further includes a patient sensor that detects position and movement of the head of said patient and produces corresponding data signals, and a microphone that produces a data signal that indicates detected sounds produced by said patient.

10 55. A method as defined in claim 52, further including providing the patient physiological data signals to a computing system that analyzes the patient physiological data signals and identifies any abnormal respiratory events of the patient, thereby producing one or more secondary respiratory event signals that are provided to the expert system.

15 56. A method as defined in claim 52, further comprising providing said pulse oximetry data signals to computing circuitry that responds to the received data signals by identifying a respiratory event of the patient, wherein the computing circuitry identifies said respiratory event in response to detecting pulse oximetry data signals that indicate
20 oxyhemoglobin desaturation.

57. A method as defined in claim 52, wherein the pulse oximetry data signal values necessary to indicate oxyhemoglobin desaturation and comprising a respiratory event of the patient are variable.

5 58. A method as defined in claim 52, whereby the level of oxyhemoglobin desaturation required to determine a respiratory event is variable.

59. A method as defined in claim 52, wherein the level of oxyhemoglobin desaturation required to determine a respiratory event is variable, and wherein the variable
10 level is based on a predetermined relationship between the partial pressure of oxygen and oxyhemoglobin saturation.

60. A method as defined in claim 52, wherein the level of oxyhemoglobin desaturation required to determine a respiratory event is variable, and the variable level is
15 based on at least one of the following criteria: peak oxyhemoglobin saturation, or nadir, or peak oxyhemoglobin resaturation.

61. A method as defined in claim 49, further including:
receiving light from multiple light sources of an SpO_2 measuring circuit at a photo
20 diode that produces a photo diode current having an AC component and a DC component;
producing a difference signal at an input of an analog-to-digital converter, wherein the difference signal comprises the difference between the photo diode current and a substantially

constant current produced by a controlled current source, such that the analog-to-digital converter produces a measurement current in response, wherein the constant current is selected such that the difference input signal has an AC component that is substantially equal to its DC component.

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62. A method as defined in claim 49, further comprising:

receiving patient SpO₂ data produced by the pulse oximetry sensor; and

~~smoothing the data by performing one or more of the following smoothing operations:~~

(a) applying a moving window median filter that replaces a current data sample value with a
10 median value selected from a predetermined number of data sample values, (b) applying a
slew limitation filter that determines if two consecutive data sample values differ by more
than a predetermined amount, and in response replaces a data sample value with a
replacement value so as to limit the difference to no greater than the predetermined amount,
and (c) applying an averaging technique that operates on multiple data sample values.

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63. A method as defined in claim 62, wherein the averaging technique comprises a first-order infinite impulse response (IIR) filter that operates on a current data sample value and a previous data sample value.

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64. A method as defined in claim 62, wherein more than one of the multiple smoothing operations is performed, and one or more of the smoothing operations receives, as data input, smoothed data sample values produced by a different smoothing operation.

65. A method as defined in claim 49, further including receiving patient SpO₂ data produced by the pulse oximetry sensor and identifying SpO₂ data that indicates desaturation occurrences in accordance with rate of change of SpO₂ desaturation data.

66. A method as defined in claim 49, further including receiving patient SpO₂ data produced by the pulse oximetry sensor and identifying SpO₂ data that indicates desaturation ~~related to abnormal respiratory events by identifying changes in patient physiological data~~ that indicate patient arousal.

67. A method as defined in claim 66, wherein the changes in patient physiological data include one or more of changes in patient heart rate, patient position and movement, and patient produced sounds.

68. A method as defined in claim 49, wherein the pulse oximetry sensor comprises an active pulse oximetry sensor that applies positive pressure on the patient.

69. A method as defined in claim 49, wherein the physiological monitoring system is affixed to the patient by an adjustable strap.

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70. A physiological monitoring system comprising:

a pulse oximetry sensor and circuitry that detects oxyhemoglobin saturation and pulse rate of the patient and produces corresponding data signals;

5 a patient sensor that produces a signal that indicates position and movement of the head of said patient;

a microphone that produces a signal that indicates detected sounds produced by said patient;

~~power means for providing electrical energy to the sensors for operation; and~~

10 memory means for storing the data signals produced by said pulse oximetry sensor, said patient sensor, and said microphone;

wherein said sensors and power means are affixed on said patient's body to detect the patient conditions and produce the data signals, thereby monitoring said patient's condition.

71. A system as defined in claim 70, further comprising computing circuitry that
15 receives said pulse oximetry data signals and identifies a respiratory event of the patient, wherein the computing circuitry identifies said respiratory event in response to detecting pulse oximetry data signals that indicate oxyhemoglobin desaturation.

72. A system as defined in claim 71, wherein the pulse oximetry data signal
20 values necessary to indicate oxyhemoglobin desaturation and comprising a respiratory event of the patient are variable.

73. A system as defined in claim 71, whereby the level of oxyhemoglobin desaturation required to determine a respiratory event is variable.

74. A system as defined in claim 71, wherein the level of oxyhemoglobin desaturation required to determine a respiratory event is variable, and wherein the variable level is based on a predetermined relationship between the partial pressure of oxygen and oxyhemoglobin saturation.

75. A system as defined in claim 71, wherein the level of oxyhemoglobin desaturation required to determine a respiratory event is variable, and the variable level is based on at least one of the following criteria: peak oxyhemoglobin saturation, or nadir, or peak oxyhemoglobin resaturation.

76. A system as defined in claim 71, wherein the pulse oximetry sensor comprises an active pulse oximetry sensor that applies positive pressure on the patient.

77. A system as defined in claim 71, wherein the physiological monitoring system is affixed to the patient by an adjustable strap.